

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW HAMPSHIRE

Marine Polymer Technologies, Inc.

v.

Civil No. 06-cv-100-JD  
Opinion No. 2010 DNH 127

HemCon, Inc.

O R D E R

The determination of obviousness is a legal issue for the court to decide, based on underlying factual findings. See Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Before trial, the parties submitted requests for findings of fact and rulings of law, which included the issue of obviousness. The factual issues pertaining to obviousness, however, were tried to the jury. At the close of HemCon's case on invalidity, Marine Polymer moved for judgment as a matter of law on all of the invalidity defenses. The court granted judgment as a matter of law in Marine Polymer's favor on the defenses of lack of a written description, lack of enablement, and natural product but reserved judgment on the defenses of anticipation and obviousness.

The jury found in Marine Polymer's favor on anticipation and on the factual issues pertaining to obviousness. After the verdict, HemCon filed a motion for judgment as a matter of law

and for a new trial on anticipation and obviousness, which was denied. The court now makes the obviousness determination.

Under 35 U.S.C. § 103, patent claims are invalid due to obviousness if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 399 (2007) (quoting § 103). The underlying factual issues pertaining to obviousness include “the scope and content of the prior art, the differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and secondary considerations, otherwise known as objective indicia of nonobviousness.” Ecolab, Inc. v. FMC Corp., 569 F.3d 1335, 1349 (Fed. Cir. 2009) (internal quotation marks omitted). Invalidity due to obviousness must be proven by clear and convincing evidence. Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1338 (Fed. Cir. 2010); Fresenius USA, Inc. v. Baxter Int’l, Inc., 582 F.3d 1288, 1294-95 (Fed. Cir. 2009).

The asserted claims of the ‘245 patent are claims 6, 7, 10, 11, 12, 17, and 20. The invention claimed by the asserted claims is biocompatible poly-β-1→4-N-acetylglucosamine and biocompatible poly-β-1→4-glucosamine with certain other elements. The asserted

claims for biocompatible poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine include limitations for certain numbers of monosaccharides covalently attached in a  $\beta$ -1 $\rightarrow$ 4 conformation, certain molecular weights, certain amounts of deacetylation, and an elution test score of 0. The asserted claims for biocompatible poly- $\beta$ -1 $\rightarrow$ 4-glucosamine include limitations for numbers of monosaccharides and an elution test score of 0. The terms "biocompatible poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine" and "biocompatible poly- $\beta$ -1 $\rightarrow$ 4-glucosamine" were construed to mean:

polymers with their stated compositions (poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine and poly- $\beta$ -1 $\rightarrow$ 4-glucosamine) and with low variability, high purity, and no detectable biological reactivity as determined by biocompatibility tests.

Before trial, HemCon requested findings related to obviousness on the level of ordinary skill, scope and content of the prior art, and differences over the prior art.<sup>1</sup> Marine Polymer requested findings on the level of ordinary skill, claim construction, and HemCon's expert's opinions on obviousness based on the prior art. The parties later agreed on the scope and content of the prior art, which consisted of the following:

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<sup>1</sup>HemCon's requests directed to the differences over prior art stated generally, without reference to particular prior art, that the claimed chemical compositions were not different from disclosed chemical compositions and that any differences in the chemical compositions would be minor and obvious.

- 1) Paul A. Sandford, "Chitosan: Commercial Uses and Potential Applications, published in Chitin and Chitosan: Sources, Chemistry, Biochemistry, Physical Properties and Applications at pages 51 - 59 (1989);
- 2) Paul A. Sandford, "Biomedical Applications of New Forms of Chitin/Chitosan" (1992);
- 3) Protasan Trade Brochure;
- 4) United States Patent Number 4,394,373 (Malette), and
- 5) United States Patent Number 3,533,940 (Peniston, et al.).

At trial, Dr. Sandford testified that he used "biocompatible" in his 1989 article as a general term that meant many different things to different people. Dr. Sandford acknowledged that the term biocompatible, as used in his article, referred to the application of p-GlcNAc material and did not disclose testing for biocompatibility. HemCon's expert witness, Dr. Dornish, testified that Dr. Sandford's 1989 article disclosed biocompatible p-GlcNAc because it disclosed medical uses which required no biological reactivity and that the '373 patent to Mallette similarly disclosed p-GlcNAc with little or no biological reactivity because of the suggested uses. On cross-examination, Dr. Dornish explained that his opinions were based on a definition of biocompatibility that the material's use or application determines its biocompatibility.

Marine Polymer's expert witness, Dr. Langer, testified at trial that the cited prior art references did not disclose the properties of biocompatible poly- $\beta$ -1-4-N-acetylglucosamine and biocompatible poly- $\beta$ -1-4-glucosamine. In particular, Dr. Langer explained that the prior art did not disclose p-GlcNAc with no detectable biological reactivity as determined by biocompatibility tests.

The parties agreed to a jury verdict form, which was submitted to the jury. The jury found that the applicable level of ordinary skill in the field was "at least a bachelor's degree in engineering, material science, biology, or a related discipline, and at least two years of practical experience with biomaterials." With respect to the differences between the prior art and the claimed invention, the jury found that none of the properties of biocompatible poly- $\beta$ -1-4-N-acetylglucosamine and biocompatible poly- $\beta$ -1-4-glucosamine were disclosed in the prior art. The jury also found in Marine Polymer's favor as to the objective factors of nonobviousness and found that HemCon failed to establish either of the factors tending to show obviousness.

In its motion for judgment as a matter of law or a new trial, HemCon argued that the jury's findings concerning the differences between the prior art and the claimed invention, pertaining to obviousness, were not supported by the evidence.

HemCon also disputed two of the jury's findings and argued that the asserted errors undermined the jury's other findings. The court concluded that the jury's findings were supported by the evidence, that the verdict form was answered correctly, and that the findings did not support an inference that the jury did not properly render its verdict. The motion was denied.

For purposes of making the obviousness determination here, the court accepts the jury's factual findings, which are amply supported by the evidence at trial.<sup>2</sup> With respect to the jury's findings that the prior art did not disclose poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine or poly- $\beta$ -1 $\rightarrow$ 4-glucosamine, the jury correctly determined that neither biocompatible poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine nor biocompatible poly- $\beta$ -1 $\rightarrow$ 4-glucosamine was disclosed in the prior art. The jury also found that the prior art did not disclose the listed properties of biocompatible poly- $\beta$ -1 $\rightarrow$ 4-N-acetylglucosamine and biocompatible poly- $\beta$ -1 $\rightarrow$ 4-glucosamine, as claimed in the '245 patent. Based on the jury's findings, the prior art did not disclose the claimed invention.

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<sup>2</sup>HemCon's requests for findings pertaining to the chemical compositions of the claimed invention and prior art are not pertinent to the obviousness determination in this case which focuses on the meaning of biocompatible as claimed in the '245 patent. To the extent HemCon merely asserts that chitin and chitosan, without a limitation for biocompatibility, were disclosed in the prior art, that does not appear to be a disputed issue.

Therefore, the asserted claims of the '245 patent were not obvious and are valid.

Conclusion

For the foregoing reasons, the court rules that HemCon did not prove by clear and convincing evidence that the asserted claims of the '245 patent were obvious in light of the prior art. Therefore, the counterclaim and defense of obviousness are denied.

SO ORDERED.

  
Joseph A. DiClerico, Jr.  
United States District Judge

July 27, 2010

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